RVD2008-22

Re-evaluation Decision

Dodine

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Overview

Re-evaluation Decision

After a re-evaluation of the fungicide dodine, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing dodine for sale and use in Canada.

An evaluation of available scientific information found that products containing dodine do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of dodine uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of dodine was first presented in Proposed Re-evaluation Decision PRVD2008-11, *Dodine*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of dodine as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-11. To comply with this decision, registrants of products containing dodine will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Dodine, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of dodine. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated dodine and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-11, *Dodine*.

What Is Dodine?

Dodine, or dodecylguanidine acetate, is a salt of a strong base, dodecylguanidine. It is a fungicide that is used to control fungi infecting the leaves and fruit of certain crops. Farm workers may apply dodine using groundboom spray equipment and airblast equipment.

Dodecylguanidine hydrochloride is of similar chemical composition and properties as dodine and was considered bioequivalent and toxicologically the same as dodine in the 2005 RED. In Canada, dodecylguanidine hydrochloride is registered for similar industrial antimicrobial uses as in the United States (i.e. slimicide in recirculating cooling waters, pulp and paper mills, and preservative for paper products, coatings and adhesives) but is not currently under re-evaluation in Canada. Conclusions on risks are relevant for the purposes of the re-evaluation of dodine. This document does not represent a proposed re-evaluation decision for the registered Canadian uses of dodecylguanidine hydrochloride.

Health Considerations

Can Approved Uses of Dodine Affect Human Health?

Dodine is unlikely to affect your health when used according to the revised label directions.

People could be exposed to dodine through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. People could be exposed to dodecylguanadine hydrochloride indirectly from food packaged in paper or paper board made using this slimicide/preservative. Infants who wear disposable diapers impregnated with dodecylguanadine hydrochloride may also be exposed. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that dodine was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Dodine is currently registered in Canada for use on apples, cherries, pears and strawberries and could be used in other countries on crops that are imported into Canada. MRLs for dodine are established for the following commodities:

- apples, pears, strawberries at 5.0 ppm
- cherries at 2.0 ppm

Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Dodine Is Introduced Into the Environment?

Dodine is unlikely to affect non-target organisms when used according to the revised label directions.

Terrestrial and aquatic non-target organisms could be exposed to dodine in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a low risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of dodine was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA requires aquatic and terrestrial buffer zones for liquid and wettable powder formulations of dodine to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of dodine, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval to protect workers entering treated sites

Environment

- Additional advisory label statements to reduce potential surface water and groundwater contamination
- Buffer zones to protect non-target, sensitive aquatic and terrestrial habitats
- Changes to the maximum single application rate and to limit the number of yearly applications

Appendix I lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on dodine within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Dodine

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section.

> All handlers must wear a long-sleeved shirt and long pants. In addition, wear chemical-resistant gloves and a chemical-resistant apron during mixing/loading activities. Chemical-resistant gloves should also be worn during repair and clean-up activities.
>
> DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 48 hours.
>
> DO NOT apply this product in a way that it will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area being treated during application.
>
> Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. DO NOT reuse them.
>
> Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

II) The following statements must be included in the **DIRECTIONS FOR USE** section:

> **Apples**
> DO NOT apply more than 10.2 kg a.i./ha/year.
> DO NOT apply more than 2 applications per year at a rate of 2.2 kg a.i./ha/application.
> DO NOT apply more than 4 applications per year at a rate of 1.46 kg a.i./ha/application.
> DO NOT apply less than 7 days from the last application.
> DO NOT apply within 7 days of harvest.

Cherries (sour and sweet)
DO NOT apply more than 5.8 kg a.i./ha/year.
DO NOT apply more than 2 applications per year at a rate of 1.46 kg a.i./ha/application.
DO NOT apply more than 4 applications per year at a rate of 0.73 kg a.i./ha/application.
DO NOT apply less than 7 days from the last application.
DO NOT apply within 7 days of harvest.

Pears
DO NOT apply more than 10.2 kg a.i./ha/year.
DO NOT apply more than 2 applications per year at a rate of 2.2 kg a.i./ha/application.
DO NOT apply more than 4 applications per year at a rate of 1.46 kg a.i./ha/application.
DO NOT apply less than 7 days from the last application.
DO NOT apply within 7 days of harvest.

Strawberries
DO NOT apply more than 1.46 kg a.i./ha/application.
DO NOT apply more than 5 times per year.
DO NOT apply less than 7 days from the last application.
DO NOT apply within 14 days of harvest.

To reduce runoff from treated areas into aquatic habitats, consider the characteristics and conditions of the site before treatment. Site characteristics and conditions that may lead to runoff include but are not limited to the following: heavy rainfall, moderate to steep slope, bare soil, poorly draining soil (e.g. soils that are compacted or fine-textured, such as clay).

Avoid application of this product when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) classification of "fine". Boom height must be 60 cm or less above the crop or ground.

Airblast application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. DO NOT apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer, or spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial Habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Strawberries		70	35	2	1	1
Airblast	Apple, pear	Early growth stage	65	55	25	15	2
		Late growth stage	55	45	15	10	1
	Cherry	Early growth stage	60	50	20	10	2
		Late growth stage	50	40	10	5	1

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

> TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.
>
> To reduce runoff from treated areas into aquatic habitats, avoid application to areas with a moderate to steep slope, compacted soil, or clay.
>
> Avoid application when heavy rain is forecast.
>
> Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.